## 1. Scientific Abstract.

**TITLE OF PROJECT:** **(Study IR850-170)** A Phase I, Open Label Safety Study of Allogeneic Glioblastoma Tumor Cell Lines Mixed with Allogeneic Fibroblasts Genetically Modified to Secrete GM-CSF in Patients with Glioblastoma Multiforme or Anaplastic Astrocytoma. Immune Response Corp, Carlsbad, California.

Standard therapy for patients with malignant gliomas consists of surgical resection, followed by external-beam radiation alone, or in combination with adjuvant nitrosourea-based chemotherapy. Despite treatment, most patients with glioblastoma multiforme eventually develop recurrent disease with a 9 to 11 month median survival from the time of diagnosis. For patients with anaplastic astrocytoma median survival times range from 18-64 months depending on the report. Effective treatment options at the time of recurrence are limited.

In recent years, immunotherapy has become a major focus of investigational treatment of cancer. Active immunotherapy involves the use of either autologous or allogeneic tumor cells, altered in some way to enhance their immunogenicity; these are then administered to patients. Previous studies using tumor cells secreting GM-CSF have shown potential efficacy in several different types of cancer by inducing tumor-specific immune responses with minimal toxicity.

The purpose of this study is to determine safety and preliminary immune response in patients with glioblastoma multiforme or anaplastic astrocytoma who are treated with the Glioma Cancer Vaccine. This is a Phase I, open label, single center, single dose study of an allogeneic Glioma Cancer Vaccine in patients newly diagnosed with glioblastoma multiforme or anaplastic astrocytoma. The Glioma Cancer Vaccine consists of three allogeneic human glioma tumor cell lines mixed with IR851, a human fibroblast line which secretes a cytokine, GM-CSF.

The total vaccine dose will be divided equally and administered into 3 separate limbs for each immunization cycle. The amount of GM-CSF secreted in the total vaccine dose is 6000± 1000 ng/24 hours. A total of 12 patients will be enrolled. Half of the patients will be HLA-A2 positive and half will be HLA-A2 negative.

Patients will be monitored for safety, toxicity and for specific cellular and humoral immune responses up to 16 weeks after immunization. Disease progression will also be monitored.